Re: Opposition to Senator Durbin's bill S1310, the "Dietary Supplement Labeling Act" and new proposed FDA regulations for supplements.

Dear Senator:

I am writing to express my strong opposition to Senator Durbin's recently proposed legislation, S1310, the "Dietary Supplement Labeling Act." On the Friday before the July 4th weekend, Senator Durbin - hoping his actions would not be carried in the media before a major holiday - introduced this bill. Though couched in noble terms about consumer protection, the bill really seems designed to give the Food and Drug Administration extraordinary new levels of regulatory authority over dietary supplements, which it does not need to perform its job, and which will add new onerous regulatory hurdles onto legitimate, honest supplement manufacturers in this country.

The FDA already has the authority to supervise supplement manufacture, to regulate labeling, and remove harmful or dangerous supplements from the marketplace. It has already put in place very stringent "Good Manufacturing Practice" regulations that promote standards and require manufacturers to provide the highest quality, legitimate products to consumers. I believe this new legislation is part of an ongoing pattern to eliminate the availability of legitimate supplements so that Americans have no choice in their health care.

About the same time Senator Durbin proposed his legislation, the FDA itself announced its plans to enforce an entire new set of rules on supplement manufacturers that are so onerous, we doubt few if any companies could remain in business. In 1994, Congress passed the "Dietary Supplement Health and Education Act" (DSHEA), which in once sense did protect nutritional supplements available at the time and their suppliers from FDA over-regulation and overt FDA harassment. However, the bill also gave the FDA enormous power over any *new* supplements that might be developed after 1994, with the authority to require the expensive, and time consuming process normally reserved for synthetic pharmaceuticals before these new supplements could be approved and made available to consumers. Basically, if implemented, supplements would remain stuck in 1994, with manufacturers unable to provide new products in response to ongoing research in the field.

Furthermore, by enforcing this provision in DSHEA, the FDA could require supplements available prior to 1994 that have undergone any change whatsoever to undergo re-assessment, with the possibility that these products might be removed from the market until the lengthy review was completed. Apparently, even if the particle size of a supplement has changed since 1994, the manufacturer would be required to petition the FDA for approval of the product. Experts we have consulted who have read the new, complicated regulations feel that, in their opinion, any supplement manufacturer might be at risk and few could financially survive should the FDA enforce to the letter the regulations that it presented last week.

Nutritional supplements, because of the concern and integrity of the great majority of manufacturers, are extraordinarily safe and the FDA knows this. Currently, all supplements in the US must be manufactured in compliance with the strict FDA Good Manufacturing Practices. The FDA already has the power it needs to "protect" the consumer. These regulations are unnecessarily onerous and unreasonable.

Americans by the tens of millions use supplements daily, and want these products to remain available to them. I believe that nutritional supplements have great value and when used properly are health promoting

For further information I suggest you consult the following website: http://www.anh-usa.org/

Please help stop Senator Durbin's bill. Please reign in an out-of-control FDA. We want and need our nutritional supplements to remain freely available without undue FDA intrusion.

Sincerely,